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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
CARLSON, KAREN C

ART UNIT	PAPER NUMBER
1653	29

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/962,560	HILTON ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-12 and 41-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-12 and 41-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *26* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of proteins (SEQ ID NO: 4, 10, 12) encoding mouse, human, and rat SOCS1 protein, nucleic acid encoding said proteins (SEQ ID NO: 3, 9, and 11), and SOCS boxes having SEQ ID NO:52 and 55 in Paper No. 28, filed January 8, 2002, is acknowledged. The traversal is on the ground(s) that the molecules of the SOCS family are related in structure and in function. Specifically, the conserved structure is defined in SEQ ID NO:51. This argument is not persuasive. Each amino acid presented in SEQ ID NO:51 can be conservatively and nonconservatively substituted, can be deleted, or represent multiple amino acids and therefore the structure is not conserved. One skilled in the art would not recognize that these sequences represent a conserved region within a family of proteins

For example, alignment of the SOCS box in mouse SOCS1, SOCS2, and SOCS3 protein shows that there is little if any overlapping sequence:

```
mSOCS1 box; SEQ ID NO:52:  VRPLQ ELCRQ RIVAA  VGREN LARIP LNPVL RDYL
                             ||   ||          |         |         |||
mSOCS2 box; SEQ ID NO: 53: APTLQ HFCRL  AINKC  TGTIW  GLPLP TRLK   DYL
                           |||| ||   |                             |
mSOCS3 box; SEQ ID NO:54:  VATLQ HLCRK TVNGH LDSYE  KVTQL PGPIR   EFL
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Therefore, in terms of structure, the nucleic acid sequences encoding these protein sequences are properly restricted as patentably distinct.

Applicants urge that all of the SOCS proteins have similar function and refer to the capacity to modulate signal transduction. Applicants do not expound on this capacity, that is, interleukin-6 versus TNF, growth hormone, glutamate, ion channel, and so forth. Which signal transduction of the millions that occur daily in the body, does Applicant refer to?

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5 and 14-40 have been canceled. Claims 6-12 and 41-67 are currently pending and are under examination in-so-far as they pertain to the elected SOCS1 proteins and nucleic acid encoding SOCS1 proteins.

The disclosure is objected to because of the following informalities: Sequence identification numbers have not been placed throughout the specification – see page 6, line 9, for example. Also, all amino acids should be written using the 3 letter code – see 37 CFR 1.821 and Applicants figures, for example. It is improper to incorporate sequences into the specification –see page 76, for example.

Appropriate correction is required.

This application has been filed with informal drawings which are acceptable for examination purposes only. See the PTO-948 attached to Paper #15, mailed February 24, 2000. Formal drawings will be required when the application is allowed.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 62-67 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 of prior U.S. Patent No. 6,323,317. This is a double patenting rejection.

Claim 62 is drawn to a protein comprising a SOCS box comprising amino acid sequence 52 or 55, or having 70% similarity to SEQ ID NO: 52 or 55. SEQ ID NO: 52 and NO: 55 are the same as patent sequences SEQ ID NO: 64 and NO: 67, respectively. Therefore, the limitations of Claim 62 is the same as patent Claims 3 and 4. SEQ ID NO: 52 is derived from mouse and rat, while SEQ ID NO: 55 is derived from human, and such corresponds to SEQ ID NO: 64 and NO: 67; therefore,

Claim 64 is encompassed or inherent to patent Claims 3 and 4. The sequences of SEQ ID NO: 52 and 55 are found in the variables set forth for SQ ID NO:59 of patent Claims 1 and 2; therefore, when these variables are set to the amino acids depicted in SEQ ID NO: 52 and NO: 55 the claim limitations are the same.

Claim 65 is the same as patent Claim 5.

The limitations of Claim 66 are found in each of patent Claims 6 and 7.

The limitations of Claim 67, that the signal transduction is mediated by IL-6, are found in each of patent Claims 8, 9, and 10.

Instant Claim 63 is drawn to a protein comprising amino acid sequences SEQ ID NO:4, NO:10, or NO:12, or sequences having 50% similarity thereto. These sequences are identical to patent SEQ ID NO: 4, NO: 10, and NO:12 and therefore meet the limitations of patent Claim 11. These sequences are encoded by SEQ ID NO: 3, NO: 9, and NO: 11, respectively, which are the same as in the patent, and therefore limitations of patent Claim 12 are the same as Claim 63.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 63-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-15 of U.S. Patent No. 6,323,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because the SOCS1 protein set forth in SEQ ID NO: 4, NO: 10, and NO:12 comprise the

SOCS box of patent Claims 1 and 2 (SEQ ID NO:59), of patent Claims 3 and 4 because these sequences comprise SEQ ID NO: 52 or NO: 55 which are the same as patent sequences SEQ ID NO: 64 and 67. Claims 65-67 depend from Claim 63 and have the same limitations as Claims 5-10. Patent Claims 13-15 are inherent to the sequences, and the specifications teaches that these sequences have the limitations of Claims 13-15. (see also the current nucleic acid claims describing these variables attributed to the protein sequences).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-12, 41-45, 47, 48, 50-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims do not present any structure and function relationship and therefore lack written description. For example, independent Claims 6 and 41 are drawn to nucleic acid encoding a protein comprising a SOCS box that can have an amazing number of varied amino acids. It is not set forth what that SOCS box look like or what function the SOCS box will give the protein claimed. Keep in mind that the SOCS box is only a part or a fragment of the entire protein. Even though Claim 42 sets forth specific sequences for the SOCS box, the function of the full-length protein claimed is not set forth. The specification does not describe proteins having a percent similarity to a sequence having any function, or nucleic acids that hybridize under any conditions to a sequence and encoding a functional protein.

To overcome this rejection for lack of written description, Applicants should place a specific function in their claims. For example, "An isolated nucleic acid encoding a protein comprising a SOCS box comprising the amino acid sequence set forth in SEQ ID NO:52 or SEQ ID NO: 55, wherein said protein inhibits IL-6-mediated signal transduction." The Examiner exemplified this claim language in the restriction requirement to aid Applicants in avoiding this rejection.

It is noted that that part of Claim 53, for example, that specifies the full-length protein sequence is enabled and meets written description because that sequence has been shown to have function.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-12, 41-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have not been amended to reflect the elected invention of SOCS1 protein, and nucleic acid encoding SOCS1 protein, and specifically to SEQ ID NOs: 3, 4, 9, 10, 11, 12, 52, and 55. Therefore, because these claims include non-elected inventions, the claims do not point out and distinctly claim the elected subject matter.

Additionally, acronyms are used throughout the claims, which render the claims indefinite. The acronyms should be spelled out in at least the independent claims to clarify the claim limitations.

In Claims 7-9, 56-58 and 65-67, it is not clear what is meant by "modulates signal transduction". Is signal transduction augmented or attenuated? Does the activity occur insider or outside the cell? That is, receptor antagonism would also "modulate signal transduction".

In Claim 53, it is not clear if a protein comprising 50% similarity to SEQ ID NO: 4, for example, must include a SOCS box having at least 70% similarity to SEQ ID NO:52 or NO:55.

Claims 56-60 depend from Claim 54. There is no mention of a protein in Claim 54 and therefore there is no antecedent basis for the protein of Claim 54 as recited in Claims 56-60.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6, 41, 7-12, 42.45, 47-48, and 50-60 are rejected under 35 U.S.C. 102(a) as being anticipated by Schluter et al. (January, 1996; Molecular Reproductive Development 43(1) 1-6). Schluter et al. teach nucleic acid submitted to GenBank as Z47352 (see page 2, col. 1 and the alignment attached to the reference. This nucleic acid sequence has 98.6% identity to SEQ ID NO:3(**Claims 45, 47, 48, 52, 53, 54**). Because SEQ ID NO:3 encodes SEQ ID NO:4 which comprises a SOCS box comprising SEQ ID NO:52 (**Claim 42, 43**) and therefore the limitations of **Claims 6, 41, and 44** are met. The limitations of **Claims 7-12, 50, 51, and 55-58** describe the protein encoded by the nucleic acid, which has no bearing on the patentability of the nucleic acid sequence.

The nucleic acid Z47352 was cloned into pUC and pGEM and isolated from cell libraries (page 2, col. 1); therefore the nucleic acid was placed into a vector (**Claim 59**) and into a host cell (**Claim 60**).

Claims 6, 41, 7-12, 42.45, 47-48, and 50-60 are rejected under 35 U.S.C. 102(a) as being anticipated by Schluter et al. (January, 1996; Molecular Reproductive Development 43(1) 1-6). Schluter et al. teach nucleic acid submitted to GenBank as Z46940 (see page 2, col. 1 and the alignment attached to the reference. This nucleic acid sequence has 99.3% identity to SEQ ID NO:9 (**Claims 45, 47, 48, 52, 53, 54**). Because SEQ ID NO:9 encodes SEQ ID NO:10 which comprises a SOCS box comprising SEQ ID NO:55 (**Claim 42, 43**) and therefore the limitations of **Claims 6, 41, and 44** are met. The limitations of **Claims 7-12, 50, 51, and 55-58** describe the protein encoded by the nucleic acid, which has no bearing on the patentability of the nucleic acid sequence.

The nucleic acid Z46940 was cloned into pUC and pGEM and isolated from cell libraries (page 2, col. 1); therefore the nucleic acid was placed into a vector (**Claim 59**) and into a host cell (**Claim 60**).

Claims 6, 41, 7-12, 42-60 are rejected under 35 U.S.C. 102(a) as being anticipated by Schluter et al. (January, 1996; Molecular Reproductive Development 43(1) 1-6). Schluter et al. teach nucleic acid submitted to GenBank as Z46939 (see page 2, col. 1 and the alignment attached to the reference. This nucleic acid sequence has 100% identity to SEQ ID NO:11 (**Claims 45, 46, 47, 48, 49, 52, 53, 54**). Because SEQ ID NO:11 encodes SEQ ID NO:12 which comprises a SOCS box comprising SEQ ID NO:52 (**Claim 42, 43**) and therefore the limitations of **Claims 6, 41, and 44** are met. The limitations of **Claims 7-12, 50, 51, and 55-58** describe the protein encoded by the nucleic acid, which has no bearing on the patentability of the nucleic acid sequence.

The nucleic acid Z46940 was cloned into pUC and pGEM and isolated from cell libraries (page 2, col. 1); therefore the nucleic acid was placed into a vector (**Claim 59**) and into a host cell (**Claim 60**).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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April 17, 2002

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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